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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,869	03/04/2004	Hubert Jansen	06478.1500	5244
22852	7590	12/23/2009		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER WIEST, PHILIP R	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 12/23/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/791,869

**Applicant(s)**

JANSEN ET AL.

**Examiner**

Philip R. Wiest

**Art Unit**

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-20 and 23-39 is/are pending in the application.
- 4a) Of the above claim(s) 36-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-20 and 23-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/6/09 has been entered.

### ***Response to Amendment***

In the reply filed 10/23/09, applicant amended claims 12 and 26, cancelled claim 22, and added new claims 35-39. Claims 12-20 and 23-39 are currently pending, and claims 36-39 are withdrawn from consideration, as discussed below.

### ***Election/Restrictions***

Newly submitted claims 36-39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 36-39 are drawn to a transfer device having a *conical* piercing mandrel that comprises both a piercing portion and a sealing portion (i.e. the piercing portion and sealing portion are substantially conical and there is no step between the portions). Conversely, the previously claimed device requires a step between the piercing portion and the sealing portion, while the sealing portion has a substantially conical shape.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 36-39 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 12, 13, 15-18, and 23-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Dudar et al. (US 5,211,638). Dudar et al. (hereafter Dudar) teach a fluid transfer device comprising a lid portion and an edge portion formed integrally with said edge portion to form a receiving cap. The receiving cap defining therein a space configured to receive the bead of a container closed by an elastic stopper (Figure 36), and the edge portion extends downward and outward so as to substantially cover the top portion of the inserted container. The elastic stopper has an internal surface configured to face the interior of the container. The edge portion has notches 764a-d such that it is configured to center the bead of a container within the space when the bead is substantially disposed in the space. The device further comprises a piercing mandrel projecting into the space so as to pierce the stopper when the bead is disposed

in the space, wherein the piercing mandrel has a flow path extending therethrough to transfer fluid. The piercing mandrel comprises a conical piercing portion 756 configured to pierce the stopper and a sealing portion (tapered sidewall 754) formed integrally with and extending from the lid portion, said sealing portion having a substantially tapered shape and contacting the elastic stopper when the bead is disposed in the space. The transition between the piercing and sealing portions is substantially stepless. When the bead is disposed in the space, the distance between the base of the sealing portion (i.e. adjacent the lid portion) and the distal end of the sealing portion is greater than the distance between the base of the sealing portion and the external surface of the elastic stopper (i.e. the sealing portion extends into the elastic stopper). Additionally, the piercing portion is disposed further away from the lid portion than the retaining notches 764a-d.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 14, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dudar in view of Larson (US 3,977,555). Dudar teaches the device substantially as claimed, but does not specifically teach that the sealing portion of the piercing mandrel is substantially stepped. Larson teaches a vial adapter for transferring

medical fluids comprising a piercing mandrel having a bulbous, stepped sealing portion 66 and a needle-shaped piercing portion extending therefrom. The bulbous sealing portion serves to stretch the elastic stopper so as to ensure complete penetration by the needle-like piercing portion (see abstract). This system also causes the bulbous portion to be pressed firmly against the stopper, thereby creating a seal between the bulbous portion and the stopper. The use of a stepped, bulbous piercing mandrel is therefore known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the piercing mandrel of Dudar with Larson's stepped bulbous proximal portion so as to ensure complete penetration of an elastic stopper when a medical fluid container is inserted into the interior space. \

3. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dudar in view of Meyer (US 5,358,501). Dudar teaches the device substantially as claimed, wherein the sealing portion has an end face at the proximal end thereof that creates an annular seal (@ 774, Figure 36). Dudar, however, does not specifically teach the use of an o-ring sealing means around the end face. Dudar, however, clearly discloses the creation of a fluid tight seal at the intersection of the lid portion and the sealing means, thus motivating one skilled in the art to include a seal that fits round openings. The use of o-rings for sealing means in medical devices is known in the art for this purpose. Meyer discloses a storage bottle containing a constituent of a medical solution, which employs an o-ring as a sealing element between the two containers. Thus, it would be obvious to one skilled in the art to apply the o-ring of Meyer to the fluid

transfer device of Dudar because doing so will achieve an effective and inexpensive sealing means, thereby preventing the loss of fluid around the edges of the vial.

### ***Response to Arguments***

Applicant's arguments have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. Specifically, Neidospial does not teach a vial adapter wherein the lid portion is formed integrally with the edge portion and the piercing mandrel. However, upon further consideration, a new ground(s) of rejection is made in view of newly discovered prior art (the Dudar patent).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/  
Examiner, Art Unit 3761

/Leslie R. Deak/  
Primary Examiner, Art Unit 3761  
18 December 2009